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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,411	03/01/2002	Gary P. Schroth	9584-030-999	6226
20583	7590	09/13/2005		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER SITTON, JEHANNE SOUAYA	
			ART UNIT 1634	PAPER NUMBER
DATE MAILED: 09/13/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,411

Applicant(s)

SCHROTH, GARY P.

Examiner

Jehanne S. Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,9-12 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9-12 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 1-2, 5-7, 9-12, and 21-25 are pending in the instant application. The following rejections are newly applied. They constitute the complete set being presently applied to the instant Application. This action is NON-FINAL.

2. The declaration filed on May 23, 2005 under 37 CFR 1.131 is sufficient to overcome the Grenier et al reference.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

4. Claims 1-2, 5-7, 9-12, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chee (Chee et al; US Pregrant Publication 2002/0132221) in view of Collins.

With regard to claims 1, 2 and 7, Chee teaches a method involving decoding an array composition comprising providing an array (instant claim 12) which contains populations of microspheres or beads (coded test unit, coded substrate) which each comprise at least a first and a second subpopulation comprising a bioactive agent and an identifier binding ligand (coding oligonucleotide) which binds to a decoder binding ligand (decoding oligonucleotide), and adding the decoder binding ligand to the array to identify the location of the bioactive agents (see para 0014-0018). Chee teaches that the bioactive agent (instant claim 9) and binding ligands can be nucleic acids (para 0039) which are particularly preferred (para 0040). With regard to instant

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claim 21, Chee teaches that the bioactive agent can also be a protein (para 0042). Chee teaches that decoding occurs through the use of the decoding binding ligands that are added during the decoding step wherein the decoding binding ligand (DBL) bind either to a distinct identifier binding ligand (IBL) that is placed on the beads or to the bioactive agent itself (para 0023). Chee teaches that the array can contain only a single bead for each bioactive agent (plurality of coded test units, plurality of coded substrates), or a plurality of beads of each type (plurality of coded test units, plurality of coded substrates) (para 0035) and teaches the use of a library of bioactive agents (para 0045). Chee teaches that preferably the IBL – identifier probe and DBL-decoder probe, are nucleic acids and that the probes should be specific so as to distinguish different IBL-DBL pairs (para 0069). Chee teaches that each subpopulation of beads comprises a plurality of different IBLs and that by using different IBLs to encode each bioactive agent, the number of possible unique codes for each agent is increased (para 0074, instant claim 24). Chee teaches that the DBL can carry a label such as a flourophore (para 0068), and are preferably directly or indirectly labeled (para 0101) such that the identification of the location of individual beads (or subpopulation of beads) is carried out in the presence of the IBL (para 0102-0104, “decoding oligonucleotide produces a detectable hybridization signal sufficient to distinguish the coded test unit from the plurality of coded test units”). Chee teaches that attachment of the nucleic acids to the beads can be covalent (claims 6 and 23; para 0051). Chee teaches that the bioactive agent and IBL can be different nucleic acids which are each independently linked to the bead (claims 11 and 25; para 0014, 0021). With regard to claim 10, Chee teaches that alternatively, the test moiety and coding oligonucleotide can be a single polynucleotide (para 0071), in such case the test moiety and the coding oligonucleotide can be considered to be covalently linked (claim 22).

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With regard to claims 1 and 5, although Chee teaches the use of isoguanine, isocytosine, Xanthanine, and hypoxanthanine (para 0047) as nucleic acid analogs, and suggests the use of such in the nucleic acids and probes of the invention taught by Chee, Chee does not specifically teach the use of such orthogonal nucleobases in the decoding binding ligand. Chee, however, does teach that the DBL-IBL nucleic acid pairs should be specific (para 0100). Collins teaches that orthogonal nucleobases such as iso-G, iso-C, or K, can be used to reduce nonspecific binding and non specific hybridization in hybridization assays (col. 15, lines 1-21). Collins teaches that such can be applied to the use of probes on solid supports (col. 15, lines 30-33). Collins teaches that using such non natural nucleobases adds to the diversity of a library of possible sequences and enables the design of universal sequences that are as noninteracting as possible among themselves (col. 25, lines 35-45). Collins specifically teaches and demonstrates the use of such nucleobases in methods involving the reduction of non specific hybridization for the detection of target polynucleotides of interest. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the DBL-IBL nucleic acids of Chee with the use of orthogonal nucleobases, such as iso-G, iso-C, X, H, or K, as suggested by Chee and specifically taught by Collins, for the purpose of increasing the specificity of the DBL-IBL nucleic acid pairs in the decoding method of Chee. The ordinary artisan would have been motivated to provide optimal specificity for the DBL-IBL method of Chee because Chee teaches that the DBL-IBL nucleic acid pairs should be specific for each other. The ordinary artisan would have been motivated to optimize specificity of the DBL-IBL nucleic acid pairs of Chee with orthogonal nucleobases as used by Collins, because Collins

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specifically teaches that these nucleobases can be used to reduce non specific binding and hybridization in nucleic acid hybridization assays.

Conclusion

5. No claims are allowable over the cited prior art.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton

Jehanne Sitton
Primary Examiner
Art Unit 1634

9/6/05